The Custom Device

The legal and engineering interfaces of orthopedic surgery are evident in the development of custom devices such as those which orthopedic surgeons have developed for the treatment of a variety of spinal diseases and injuries. Active in this field is Charles C. Edwards, MD, Chief of Orthopedic Surgery at the University of Maryland Hospital in Baltimore, Maryland, who custom-designs, engineers and implants various devices in "last chance" orthopedic cases.

By referring to Section 520(B) (A) (ii) of the Food, Drug and Cosmetic Act as amended by the Medical Device Amendments of 1976, it is reassuring to note that the Food and Drug Administration not only considers these devices but also has specific regulations which an orthopedic surgeon may follow in using a custom device and reporting use of the custom device. According to Section 520 (b) (A) (ii), a medical device is a custom device if:

- the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and such device is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient.

In the Presidential Address which Thornton Brown, MD, read at the Annual Meeting of the American Orthopaedic Association on June 20, 1979, in Dorado Beach, Puerto Rico, Dr. Brown put forth the following question:

Is the design and development of new devices being blocked or unduly delayed by the manner in which the Bureau of Medical Devices of the Food and Drug Administration is implementing the Medical Device Amendments to the Drug and Cosmetic Act?

In order to answer this question one must first set up a factual situation and then analyze the facts presented in context with the regulations of the Food and Drug Administration. In the case where an orthopedic surgeon has developed a custom device or where a manufacturer has built the custom device to his prescription, the Food and Drug Administration would also treat the custom device under Section 520. In treating it as a custom device the Bureau of Medical Devices would neither block nor unduly delay its use. The orthopedic surgeon would have to clear the use of the medical device with the institutional review board of the hospital where he is performing the operation. In the case where an orthopedic surgeon has developed a new orthopedic implant, such as a prosthetic elbow, or where a manufacturer has developed the orthopedic implant according to his design, the Food and Drug Administration will either treat the device as a preamendment device, if it approves a Section 510(k) petition, or as an investigational device. If the Food and Drug Administration approves the Section 510(k) petition, the orthopedic surgeon must not only obtain the approval of the institutional review board, but he must also become a clinical investigator of the investigational device. There is no doubt that a clinical investigation of an investigational device is a time consuming task, but cooperation with the Bureau of Medical Devices and communication with clinical investigators in other medical specialties and with manufacturers of other medical devices will economize time.

The most well-known investigational device is the intraocular lens. Its history of regulation by the Food and Drug Administration is instructive in that a special section in the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act required that the Food and Drug Administration make intraocular lenses reasonably available to the public. The ophthalmologists and intraocular lens manufacturers worked together not only to develop clinical protocols but also to develop standards for the intraocular lens so that it could be reclassified from Class III to Class II by the Food and Drug Administration. The voluntary compliance with the proposed regulations by the intraocular lens manufacturers has resulted in a very large data base for both the manufacturers and the Bureau of Medical Devices by which both have been able to prove that the intraocular lens is safe and effective. Cooperation and

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communication among ophthalmologists, intraocular lens manufacturers and representatives of the Food and Drug Administration not only made intraocular lenses available to the public but also provided a mechanism by which new designs of intraocular lenses could be approved for investigational use.

The UCLA Extension sponsored the Medical Device Standardization Workshop July 18 to 20, 1979. Among the participants were engineers, scientists, doctors and lawyers who were able to interact with not only representatives from the Food and Drug Administration but also with representatives from medical device manufacturers. The most important outcome of this workshop was the interaction among various professionals, all of whom were dedicated to providing the best possible health care for a reasonable cost, but who differed on the question of what is the best possible method. One of the recommendations from this workshop was that product liability laws will serve to reinforce voluntary standards so that mandatory standards will not be necessary. The Food and Drug Administration seems ready to implement a voluntary standards program.

At UCLA the Human Subject Committee is the institutional review committee for the School of Medicine. The institutional review committee of a research university hospital is the key in the regulatory process of medical devices. It is therefore essential that the institutional review committee has access to information on current policy of the Food and Drug Administration. With this in mind, the UCLA School of Law has approved an extramural program in which it will send two law students each year to work in the Chief Counsel’s Office of the Food and Drug Administration. When each of these students returns to the UCLA School of Law, he will work one year with the Human Subject Committee in order to assist committee members in interpreting the regulations of the Food and Drug Administration.

In developing custom devices, it is often necessary to seek out engineers to assist in the designing and engineering of the custom devices. These engineers often work with materials which are not generally known and which may be most suitable for orthopedic implants. Still other engineers are developing non-destructive testing procedures by which orthopedic implant manufacturers may be able to test each and every orthopedic device to insure both its safety and efficacy.

Reference


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Disalcid®
(salsalate) Tablets and Capsules

Brief Summary

INDICATIONS
Disalcid is indicated for the relief of the signs and symptoms of rheumatoid arthritis, osteoarthritis, and other related rheumatic disorders.

PRECAUTIONS
As with all salicylates, caution should be exercised in the use of Disalcid in chronic renal insufficiency and peptic ulcer.

Salicylates, in large doses, displace oral anticoagulants from protein-binding sites, raising the possibilities of systemic hemorrhage. Caution, therefore, should be observed with the concomitant use of anticoagulants and Disalcid.

As with all drugs, usual precautions should be followed during pregnancy.

CONTRAINDICATIONS
Disalcid is contraindicated in patients hypersensitive to salicylates.

ADVERSE REACTIONS
Muscle reactions to salicylates (nausea, dyspepsia, heartburn) may occur occasionally.

Disalcid has not been associated with reactions causing arithmetic attacks in susceptible individuals.

DOSEAGE AND ADMINISTRATION
Adults: The usual dosage is 6 tablets or capsules daily, given as 2 tablets or capsules three times daily or 3 tablets or capsules twice daily. As with other salicylates, dosage should be titrated depending on individual response. It is recommended that the last daily dose be taken at bedtime.

Children: Disalcid has not been evaluated in children. No dosage recommendations can therefore be made for children under 12 years of age.

OVERDOSE
Symptoms: Overdose with Disalcid produces the usual symptoms of salicylism: constipation, vomiting, headache, confusion, drowsiness, sweating, hyperventilation, or diarrhea.

Treatment: Further absorption of salicylate from the GI tract should be prevented by emesis (lavage of stomach) and, if necessary, by gastric lavage.

Fluid and electrolyte imbalance should be corrected by the administration of appropriate IV therapy. Adequate renal function should be maintained. Hematocrit or hematocrit dialysis may be required in extreme cases.

How Supplied:
500 mg tablets, in bottles of 100 (NDC 0089-0149-10).
500 mg capsules, in bottles of 100 (NDC 0089-0166-10).

Caution:
Federal law prohibits dispensing without prescription.

References
13. Riker Laboratories, Inc.